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FEB 0 8 2002

510(k) SUMMARY

A. Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 (215) 256-4201 Telephone (215) 256-0818 Fax
Contact:	Florence A. Caikoski Regulatory Affairs Associate
Date Prepared:	June 20, 2001

B. Trade Name: Medcomp 14.5F Double Lumen Hemodialysis Catheter

Common Name:	Hemodialysis Catheter, Implanted
Classification:	78 MSD
C.F.R. Section:	876.5540

C. Predicate Device: K981994 Bard Opti-Flow

D. Device Description:

The Medcomp 14.5F Double Lumen Hemodialysis Catheter is a polyurethane, double lumen catheter used to remove and return blood through two-segregated lumen passages. Both lumens open at the distal tip, each with a series of side holes. The distal venous lumen is tapered and extends beyond the arterial lumen to reduce recirculation.

The lumens are connected to the extensions via a molded hub. The arterial and venous extensions are identified by red and blue luer connectors and clamps. Priming volume information is printed on the clamps for ease in identification. A removable suture wing is provided for securing the catheter after initial placement. The fixed polyester cuff allows for tissue ingrowth for long term placement.

The Medcomp 14.5F Double Lumen Hemodialysis Catheter is available in varied implantable lengths, with straight or pre-curved configurations to be determined by the prescribing physician based on insertion site and patient anatomy.

E. Intended Use:

The Medcomp 14.5F Double Lumen Hemodialysis Catheter is indicated for use in attaining long-term vascular access for hemodialysis and apheresis. It may be inserted percutaneously and is ideally placed in the internal jugular vein. Alternate insertion sites include the subclavian vein. Catheters greater than 40cm are intended for femoral vein insertion.

F. Comparison to Predicate Device:

The technological characteristics of the 14.5F Double Lumen Hemodialysis Catheter are substantially equivalent to the predicate device in terms of intended use, insertion method, anatomical location, material type, performance, labeling, manufacturing process and method of sterilization.

The difference between these devices is the implantable lengths, an expansion of the indications for use, luminal design, and priming volume identification.

G. Performance Data:

In Vitro performance data for the Medcomp 14.5F Double Lumen Hemodialysis Catheter, including tensile strength, joint strength, leakage, recirculation and flow performance demonstrate that this device is substantially equivalent to legally marketed devices intended for hemodialysis and apheresis treatments. In addition, clamp effectiveness testing was performed to assure that the clamp and extension tube interacts safely and effectively. Chemical Exposure testing was performed to demonstrate compatibility with typical site care solutions.

Clinical studies were not deemed necessary since in-vitro testing was sufficient to demonstrate safety and effectiveness by way of comparison to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 8 2002

Ms. Florence A. Caikoski
Regulatory Affairs Associate
MedComp®
1499 Delp Drive
HARLEYSVILLE PA 19438

Re: K012562
Trade/Device Name: 14.5F Double Lumen Hemodialysis Catheter
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: 78 MSD
Dated: November 20, 2001
Received: November 21, 2001

Dear Ms. Caikoski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration (21 CFR Part 807); listing (21 CFR Part 807), labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K012562

Device Name: 14.5F Double Lumen Hemodialysis Catheter

Indications for use:

THE MEDCOMP 14.5F DOUBLE LUMEN HEMODIALYSIS CATHETER IS INDICATED FOR USE IN ATTAINING LONG-TERM VASCULAR ACCESS FOR HEMODIALYSIS AND APHERESIS.

IT MAY BE INSERTED PERCUTANEOUSLY AND IS PRIMARILY PLACED IN THE INTERNAL JUGULAR VEIN.

ALTERNATE INSERTION SITES INCLUDE THE SUBCLAVIAN VEIN.

CATHETERS GREATER THAN 40CM ARE INTENDED FOR FEMORAL VEIN INSERTION.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter _____
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012562

(Optional Format 1-2-96)